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| APPLICATION NO.                        | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------|----------------------|---------------------|------------------|
| 10/749,532                             | 12/30/2003      | Mineo Yamakawa       | 042390.P15140       | 8878             |
| Raj S. Dave                            | 7590 02/13/2007 | EXAMINER             |                     |                  |
| Morrison & Fo                          | erster LLP      | WESSENDORF, TERESA D |                     |                  |
| Suite 300<br>1650 Tysons B             | lvd.            | ART UNIT             | PAPER NUMBER        |                  |
| Mclean, VA 22102                       |                 |                      | 1639                |                  |
|  |                 |                      |                     |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE |                 | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MONTHS                               |                 | 02/13/2007           | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|  |  | Application No.                            | Applicant(s)    |  |  |  |
|--|--|--|-----------------|--|--|--|
|  |  | 10/749,532                                 | YAMAKAWA ET AL. |  |  |  |
|  | Office Action Summary  | Examiner                                   | Art Unit        |  |  |  |
|  |  | T. D. Wessendorf                           | 1639            |  |  |  |
|  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |  |                 |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |  |                 |  |  |  |
| Status   |  |  |                 |  |  |  |
| 1)⊠  | Responsive to communication(s) filed on 11 De  | ecember 2006.                              |                 |  |  |  |
| 2a) <u></u> ☐  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.   |  |                 |  |  |  |
| 3)   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |                 |  |  |  |
|  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |  |                 |  |  |  |
| Dispositi  | on of Claims   |  |                 |  |  |  |
| 4)🖂  | 4)⊠ Claim(s) <u>1-7,10-12 and 15-36</u> is/are pending in the application.   |  |                 |  |  |  |
| 4a) Of the above claim(s) <u>20-31</u> is/are withdrawn from consideration.  |  |  |                 |  |  |  |
| 5)   | 5) Claim(s) is/are allowed.  |  |                 |  |  |  |
| 6)⊠  | 6)⊠ Claim(s) <u>1-7,10-12,15-19 and 32-36</u> is/are rejected.   |  |                 |  |  |  |
|  | Claim(s) is/are objected to.   |  |                 |  |  |  |
| 8)[  | Claim(s) are subject to restriction and/o  | r election requirement.                    |                 |  |  |  |
| Applicati  | on Papers  |  |                 |  |  |  |
| 9)[  | The specification is objected to by the Examine  | r.   |                 |  |  |  |
| 10) 🔲  | The drawing(s) filed on is/are: a) ☐ acco  | epted or b) $\square$ objected to by the E | Examiner.       |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |  |                 |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |  |                 |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |  |                 |  |  |  |
| Priority u   | nder 35 U.S.C. § 119   |  |                 |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  |  |  |                 |  |  |  |
|  | <ul> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> </ul> |  |                 |  |  |  |
| <ul> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li> </ul>   |  |  |                 |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |  |  |                 |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |  |  |                 |  |  |  |
|  |  |  |                 |  |  |  |
| Attachment   | t(s)   |  |                 |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |  |  |                 |  |  |  |
|  | 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  Notice of Informal Patent Application      |  |                 |  |  |  |
| Paper No(s)/Mail Date 6) Other:  |  |  |                 |  |  |  |

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### DETAILED ACTION

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## Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/11/2006 has been entered.

#### Status of Claims

Claims 1-7, 10-12 and 15-36 are pending

Claims 20-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-7, 10-12, 15-19 and 32-36 are under examination.

### Withdrawn Rejection

In view of the amendments to the claims and applicants' arguments the 35 USC 112, first paragraph rejection (written description) is withdrawn.

### Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 10-12, 15-19 and 32-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons reiterated below. [This is a new matter rejection.]

The as-filed specification does not provide support for the following amended claims for reasons given in the last Office action and reiterated below:

Claims 1 and 32 recitation of "a first solid surface"; the entire steps b and c; "wherein the peptide of step (d) discriminates between the surfactant monolayer and the first geometrical shape." Also, the claim to "the first and second surface".

### Response to Arguments

Applicants state that paragraph [0027] and [0028] discloses using both positive and negative affinity geometries to screen for peptides. As explained in these paragraphs, positive affinity is used to select desired peptides and negative affinity is used to remove unwanted peptides. The first solid surface corresponds to a positive affinity surface and the second solid surface in step b) corresponds to a negative affinity surface as described in these paragraphs. The Examiner states that the recitation "....discriminates between the surfactant monolayer and the first geometric shape" is not disclosed in paragraph [0034]. Paragraph [0034] states "The methods disclosed herein provide the advantage that the interdependence of the two binding events, one to the surface and the other to already bound surfactants, can be controlled though selective pressure for either. Accordingly, in certain aspects, the surface used for a method for identifying a peptide disclosed herein is composed at least in part, or is bound by, a surfactant. An identified phage expressing a surface-binding peptide can bind to the surfactant or to both the surface and the surfactant. Alternatively, the surfactant, for example, can be a monolayer that covers the surface such that peptides expressed on the phage bind to the surfactant but cannot bind to

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the surface." Accordingly, this section describes selectively pressuring the peptide to bind to either the surfactant monolayer or the geometric surface. By pressuring the peptide to bind to one surface or the other, the peptide is discriminating between the two surfaces as claimed. Step b recites "contacting a second solid surface comprising the self-assembled surfactant monolayer and comprising a second geometrical shape with phage that bind to the first surface, wherein phage that bind to the second surface are excluded, and wherein the non-binding phage are recontacted with the first surface." As stated above, the second solid surface corresponds to the negative affinity geometry as disclosed in paragraphs [0027] and [0028], which describes excluding peptides that bind to the negative affinity surface. Re-contacting the phage with the first positive affinity surface is disclosed in [0028], which states that "Phage that do not bind the surface with the undesirable geometrical shape and/or atomic configuration, are collected and optionally amplified and subjected to additional rounds of biopanning." Step "c) repeating step (b) " is also discloses in paragraph [0028], which states that "[t]he rounds of selection and removal can be repeated to increase the binding strength and/or specificity of identified phage." Accordingly, for the reasons described above and for the reasons stated in the

response filed on August 11, 2006, all of the claimed limitations are supported by the specification as filed. Further, for the reasons stated above and in the response filed on August 11, 2006, all of the pending rejections should be withdrawn.

In reply, none of the cited sections above refer to a first or second surface. The arbitrary designation is unclear as to the differentiating or distinguishing characteristics of the first from the second surface. Furthermore, the biopanning steps described in the specification do not seem to correspond to the claimed method. The claimed method is confusing and does not make sense. Cf. with the sections cited by applicants above, e.g., paragraph [0034].

# Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In view of the amendments to the claims and cancellation of some of the claims, the rejection of the claims 5, 6, 8, 15 and 19 under 35 U.S.C. 112, second paragraph is withdrawn. However,

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claims 1-7, 10-12, 15-19 and 32-36, as amended, are rejected under 35 USC, 112, second paragraph as follows:

The amendments to claim 1 are confusing as to what is actually being claimed. The preamble recites binding to a target in the surface in order to identify a peptide. The body of the claim recites the peptide binding to a surfactant monolayer without reciting whether the surfactant monolayer is layered with a target. Is the surfactant overlaid with the target? Does the peptide bind to the self-assembled surfactant alone? It is not clear how an exogenous peptide is expressed by a phage contained in a surfactant monolayer solid surface. Step (b) does not seem to correlate with step (a), specifically with the recitation of "wherein phage that bind to the second surface are excluded...". Furthermore, step c is unclear as to the repetition of step g. There appears a lack of correlation or relevance as to newly added limitation "wherein the peptide of step (d) discriminates between the surfactant monolayer and the first geometrical shape". The claim seems to contain several embodiments.

The terms first and second surfaces are relative terms and therefore indefinite. These terms are not defined by the claim, the specification does not provide a standard for ascertaining

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the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Since applicants have not responded to this rejection, it is believed that applicants are acquiescing therewith.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 10-12, 15-19 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Naik or Belcher or Lee in view Puentes and applicants' admission of the known prior art for reasons of record and repeated below.

Naik discloses at page 169, cols. 1 and 2 a method of identifying a silver binding peptides from a combinatorial phage display peptide library comprising contacting a phage display peptide library with a inorganic surface, as silver. Naik discloses at page 170 up to page 171 that the silver particles were analyzed by transmission electron microscope. The examination of the silver nanoparticles obtained using AG4

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peptide revealed the presence of hexagonal, spherical and triangular silver particles. The silver crystal exhibited a flat plate-like morphology. See further the Methods at page 172 which provide a detail description of the method.

Belcher discloses in the abstract a method for selective binding of amino acid oligomers to semiconductor and elemental carbon-containing materials. Belcher discloses at [0047] that "elemental carbon-containing molecule" generally refers to allotropic forms of carbon. Examples include, but are not limited to, diamond, graphite and highly ordered pyrolytic graphite (HOPG). At paragraph [0048] the "substrate" may be a microfabricated solid surface to which molecules attach through either covalent or non-covalent bonds and includes, e.g., silicon, mica, gold, silver, metal, metal alloy and combinations thereof capable of having functional groups such as amino, carboxyl, thiol or hydroxyl incorporated on its surface. The substrate may be porous, planar or nonplanar. The substrate includes a contacting surface that may be the substrate itself or a second layer (e.g., substrate or biologic material with a contacting surface) made of organic or inorganic molecules and to which organic or inorganic molecules may contact. Belcher discloses that previously it was shown that peptides may bind to

semiconductor material. Semiconductor materials useful in binding peptides include, but are not limited to gallium arsenide, indium phosphate, gallium nitrate, zinc sulfide, aluminum arsenide, aluminum gallium arsenide, cadmium sulfide, cadmium selenide, zinc selenide, lead sulfide, boron nitride and silicon. At paragraph [0054] it was disclosed that the method provides a random organic polymer pool using a Phage-display library. A Phage-display library is a combinatorial library of random peptides containing between 7 and 12 amino acids fused to the pIII coat protein of M13 coliphage, providing different peptides that are reactive with crystalline semiconductor structures or other materials. At paragraph [0055] peptide sequences have been developed with affinities for various materials such as semiconductors, and elemental carbon-containing molecules such as graphite. At paragraph [0056] Belcher discloses that using a Phage-display library, protein sequences that successfully bound to the specific crystal were eluted from the surface, amplified by, e.g., a million-fold, and reacted against the substrate under more stringent conditions. This procedure was repeated between three and seven times to select the phage in the library with the most specific binding peptides. After, e.g., the third, fourth and fifth rounds of phage selection, crystal-specific phage were isolated and their DNA sequenced, identifying the peptide binding

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that is selective for the crystal composition (for example, binding to GaAs but not to Si) and crystalline face (for example, binding to (100) GaAs, but not to (111)B GaAs).

Lee discloses at page 893, Fig. 1 a method of identifying peptide by contacting a phage library with a surface comprising a target with a geometrical shape. See the entire article.

Each of Naik, Belcher and Lee does not disclose a surface comprising a surfactant. Puentes teaches that the use of surfactant results in the preparation of wide range of shapes including rod, teardrops, and tetrapods and branched tetrapods. The shapes can be made simply by varying surfactant compositions as learned from the prototypical CdSe system. Applicants admit that typically self-assembled surfactant monolayer is well known in the art and is accomplished by either growing the SAM from solution or from the gas phase (Colorado and Lee (2001)). Accordingly, it would have been obvious to use a surfactant in the method of each of Naik or Belcher or Lee for the advantages taught by Puentes. As admitted by applicants to make a self-assembled monolayer surfactant is known in the art citing Colorado reference.

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### Response to Arguments

Applicants state that Puentes teaches the advantages of using a different type of surfactant than the claimed surfactant. Accordingly, Puentes does not provide any reason to use the claimed surfactant and actually teaches against using the claimed surfactant. Further, the fact that self-assembled monolayer surfactants are known does not mean that it would be obvious to use them in the claimed manner. As emphasized by the court in In re Lee, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002), the Examiner must present specific evidence of motivation to combine the reference on the record, not the generalized evidence relied on in the pending Action. Since the Examiner has failed to provide any motivation to utilize selfassembled monolayer surfactants in the claimed process, this rejection should be withdrawn. In addition, the claims recite "wherein the peptide of step (d) discriminates between the surfactant monolayer and the first geometrical shape." The Examiner has failed to describe why it would be obvious from Naik, Belckher or Lee to utilize the surfactant in this claimed manner.

In response, attention is drawn to Example 1 of Belcher which uses TWEEN 20 (i.e., a trademark for surface active agents (surfactant as claimed)). Furthermore, applicants' arguments

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that Puentes uses a different type of surfactant from claimed one is unclear as applicants have not provided differentiating claimed surfactant from that of Puentes. applicants recognized the self-assembled monolayer surfactant are known in the art but arque not in the manner as claimed. However, the manner it is claimed is that it is employed in a surface that gives geometrical shape (as best as the claimed can be interpreted). Thus, the purpose for which Puentes uses the surfactant is similar to the claimed use of the surfactant in the method. The method in which the surfactant can be used is taught by anyone of the primary references. One cannot show nonobviousness by attacking the references individually where the rejection is based on a combination of references. In re Young, 159 USPQ 725 (CCPA 1968). The test for obviousness under 35 USC 103 is not the express suggestion of the claimed invention in any all of the references but what the references collectively would suggest; and inferences which one skilled it in the art would reasonably be expected to drawn from the disclosure in the references. In re Preda, 159 USPQ 342 and In re Conrad, 169 UASPQ 170.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Naik or Belcher or Lee in view of applicants' admission of known prior art, as applied to claims

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1-16 and 18-19 above, and further in view of Freeman et al (Science) as reiterated below.

Naik or Belcher or Lee does not disclose a surface with a Teflon as recited in claim 17. However, Freeman at page 1629 teaches a substrate comprising Teflon. Freeman discloses that the Teflon is conventionally used as a substrate. The solution-based process taught by Freeman is extremely general encompassing numerous permutations of insulating and conducting substrates including Teflon. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use as a surface substrate, Teflon in the method of e.g., Naik as taught by Freeman. The different permutations that can be done to the conventional substrate as Teflon as taught by Freeman would provide the motivation to one having ordinary skill in the art, at the time the invention was made.

Since applicants have not responded to this rejection it is believed that applicants are acquiescing therewith.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free),

T. D. Wessendorf Primary Examiner Art Unit 1639

tdw February 3, 2007